

Remarks

In the Office action of December 14, 1992, Paper No. 10, claims 1, 2, 5, 9-11, 14-17, 20, and 24-38 are pending and were rejected. More particularly, claims 1, 20, 31, and 36 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter sought to be patented. Claims 24 and 27 were rejected under 35 U.S.C. § 102(b) as being anticipated by the Choudhury reference. Claims 1, 2, 5, 9-11, 14-17, 20, 25, 26, and 28-38 were rejected under 35 U.S.C. § 103 as being unpatentable over the Choudhury reference in view of the Kreamer reference. The disclosure was objected to because of informalities noted by the Examiner.

By this amendment, the disclosure is being amended to correct those items noted by the Examiner and another item discovered by the applicant. Claims 1, 5, 20, 24, 25, 27-29, 31, 32, 34, 36, and 37 are being amended to more particularly point out and distinctly claim the subject matter sought to be patented and to further distinguish the claims over the cited references. In view of the above, applicant requests that the rejection of claims 1, 20, 31, and 36, as amended herein, under 35 U.S.C. § 112, second paragraph, be withdrawn. New claims 39 and 40 are being added to more fully claim applicant's invention, and dependent claims 14 and 15 are being canceled.

Applicant's invention as claimed in independent claim 24, as amended herein, is directed to a transluminal arrangement for positioning a prosthesis assembly at a particular position on a wall of a lumen. The transluminal arrangement comprises a prosthesis assembly including a graft having a longitudinal bore and a self expanding spring assembly having a compressed state. The self expanding spring assembly expands the graft to substantially conform the graft at a particular position on an interior wall of a lumen after the prosthesis assembly has been positioned in the lumen and the self expanding spring assembly has been released from its compressed state. The transluminal arrangement also comprises means for containing the self

expanding spring assembly in the compressed state and means positioned in the bore of the graft for retaining the prosthesis assembly at the particular position in the lumen when withdrawing the containing means from the prosthesis assembly and releasing the self expanding spring assembly from its compressed state. In dependent claim 27, as amended herein, the transluminal arrangement further comprises means for releasing the prosthesis assembly from the retaining means after the introducer means is withdrawn from the prosthesis assembly.

The Choudhury patent is directed to a method and article for performing an aneurysm repair. Choudhury discloses a graft 22 comprising an elongated, foldable material tube 24 mounted in a collapsed formation on upper and lower convoluted expansion rings 32. Slip rings 31 pass through the foldable material tube and around expansion rings 32 to permit the expansion rings to "unwind" while still holding the foldable material tube in place. Elongated, foldable material tube 24 is collapsed around carrier line, catheter tube 34 to facilitate movement of the carrier line tube with graft 22 therearound through a blood vessel. Two expansion lead wires 44 are externally coupled to the two respective expansion rings 32 via carrier line tube 34 and a plurality of slip rings 42. The two expansion lead wires 44 are coupled to the two respective expansion rings 32 by slip couplings 46. When graft 22 is properly positioned, the two expansion lead wires 44 are manually pushed against the upper and lower, convoluted expansion rings 32, thereby causing the convolutions to move apart and form a singular ring of larger diameter. As foldable material tube 24 expands, anchoring pins 28 pierce the arterial wall on opposite sides of the aneurysm. The two expansion lead wires 44 are then withdrawn by manually pulling the wires away from the location of the aneurysm to disconnect the wires at slip couplings 46. Clearly, the two convoluted expansion rings 32 of the Choudhury graft are not self expanding spring assemblies as claimed in independent claim 24, as amended herein, and dependent claim 27, as amended herein. The convoluted expansion rings also require separate expansion lead wires to be externally coupled thereto

along the length of the carrier line tube to manually enlarge the diameter of the expansion rings. Furthermore, the Choudhury reference does not disclose means for containing a self expanding spring assembly in a compressed state as claimed in claims 24 and 27, as amended herein.

In view of the above, applicant submits that the Choudhury reference does not identically disclose the self expanding spring assemblies and means for containing the self expanding spring assembly of applicant's invention as claimed in claims 24 and 27, as amended herein, and it is requested that the rejection of these claims under 35 U.S.C. § 102(b) as being anticipated by the Choudhury reference, be withdrawn.

The Kreamer reference is directed to aneurysm repair apparatus and method. The Kreamer apparatus includes a triple balloon catheter 50 of which balloons 54, 56, and 58 are externally, sequentially inflated to expand graft 76 next to the wall of a vessel. Like the Choudhury reference, the Kreamer balloons are not self expanding and do not have means for containing them in a compressed state as claimed in applicant's invention. The Kreamer apparatus includes graft 76 which is covered with a contact adhesive for bonding the graft to the walls of the aorta and iliac arteries. The adhesive coated graft is slid over the triple balloon catheter and secured thereto by spikes which project from the equators of the three balloons. An outer sleeve with little or no affinity for the contact adhesive is then placed over the graft to protect the graft from contact with the vessel wall during insertion. The balloon catheter with the graft positioned therearound is inserted into the vessel around the tube of an occlusion catheter, which is positioned in the aorta upstream from the aneurysm. When the graft is properly positioned, the protective outer sleeve is removed, and the balloons are externally, sequentially inflated by the introduction of compressed air via separate inflation tubes 66 in the interior of the balloon catheter. The inflated balloons press the adhesive coated graft against the vessel wall to adhere the graft to the wall. Clearly, the Kreamer reference teaches the use of an outer sheath positioned around the graft

to prevent the contact adhesive positioned on the outer surface of the graft from prematurely adhering to the surface of the vessel wall during insertion thereof. The Kreamer reference does not disclose, teach, or even suggest using the outer sheath to maintain the inflation balloons of the Kreamer apparatus or the expansion rings of the Choudhury reference in a compressed state as claimed in applicant's invention. Furthermore, the Choudhury and Kreamer references, either singly or in combination, do not teach or even suggest a prosthesis having a self expanding spring assembly positioned or disposed within the bore of the introducer sheath as claimed in applicant's claims 1, 5, 20, 25, 28, 29, 31, 32, 34, 36, and 37, as amended herein, and in claims 2, 9-11, 16, 17, 26, 30, 33, 35, and 38. The Choudhury and Kreamer references are directed to a prosthesis assembly which is positioned at an aneurysm site and then externally and manually operated to expand and come in contact with the surface of the vessel wall. Applicant's claimed invention is directed to a prosthesis assembly which is self expanding and does not require the use of any external or manually operated expansion means.

In view of the above, applicant submits that the transluminal arrangement of claims 1, 5, 20, 25, 28, 29, 31, 32, 34, 36, and 37, as amended herein, and claims 2, 9-11, 16, 17, 26, 30, 33, 35, and 38, which includes a prosthesis having a graft and a self expanding spring assembly for conforming the graft to an interior wall of a lumen and also including means such as a tubular introducer sheath in which the self expandable prosthesis is positioned or disposed therein, is not taught or even suggested by the Choudhury and Kreamer references, either singly or in combination, and it is requested that the rejection of these claims under 35 U.S.C. § 103 as being unpatentable over the Choudhury reference in view of the Kreamer reference, be withdrawn.

The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, if the Examiner deems that a telephone interview would further advance the prosecution thereof, he is invited to call the applicant's attorney.

Respectfully submitted,

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